REMARKS

Claims 41 and 54 are pending in this application and are presented for examination. Claims 1-40 and 42-53 have been canceled without prejudice. Claim 41 has been amended. Claim 54 has been newly added. No new matter has been introduced with the foregoing amendment and newly added claim. Reconsideration is respectfully requested.

I. FORMALITIES

Support for amended claim 41 is found, for example, from page 4, line 22 to page 5, line 10 in the specification as filed. Support for new claim 54 is found, for example, on page 31, lines 15-19. As such, Applicants respectfully request that the amended and new claims be entered.

II. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

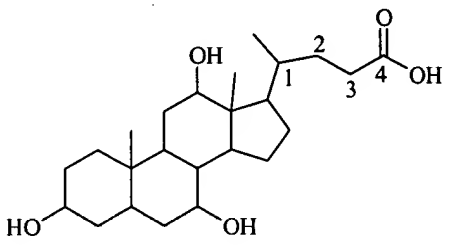
A. Written Description Rejection

Claims 41-53 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the Applicants, at the time the application was filed, had possession of the claimed invention. To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

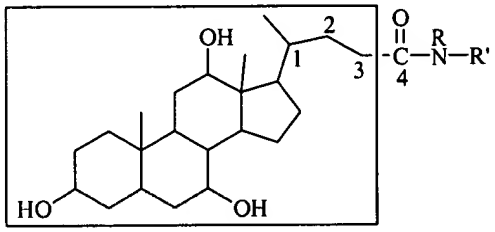
The Examiner alleges that neither is the structure of Impurity II disclosed in the application, nor is its structure readily apparent from the application as filed. In order to expedite prosecution, Applicants have amended claim 41 to clearly specify that X_1 and X_2 are both cholic acid groups, X_3 is a pentose monosaccharide group, and three carbons link the nitrogen atoms in the core of Formula I (n is 3). Applicants assert that a compound having the structure of Formula I as amended is clearly and adequately described in the specification. For instance, Example 12 specifically discloses a compound of Formula I (page 31, lines 15-19), and the specification teaches that a preferred compound of the present invention contains cholic acid groups at both X_1 and X_2, a saccharide group at X_3, and three carbons linking the nitrogen

atoms in the core of Formula I (page 5, lines 2-10). A pentose monosaccharide group is clearly defined as a saccharide group found at X_3 (page 4, lines 31-32). Further, the structure of Formula I is supported by the presentation of mass spectral data that unambiguously identifies its structure (page 31, lines 25-27). Therefore, in view of the foregoing, it is evident that the subject matter now being claimed, was described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Further, claim 54 uses IUPAC nomenclature to name and claim the compound. As such, Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 112, first paragraph rejection.

The Examiner also alleges that the specification does not define a "cholic acid group." In response, Applicants assert that, to one skilled in the art, it is abundantly clear that the phrase "cholic acid group" means that it is no longer cholic acid, but rather a derivative of cholic acid. By comparing the two structures below of "cholic acid" and "cholic acid group," the Examiner can clearly see that the only difference is that the C-O single bond in the carboxylic group of cholic acid has been substituted by a C-N amide bond upon attachment of the cholic acid to the core of Formula I.



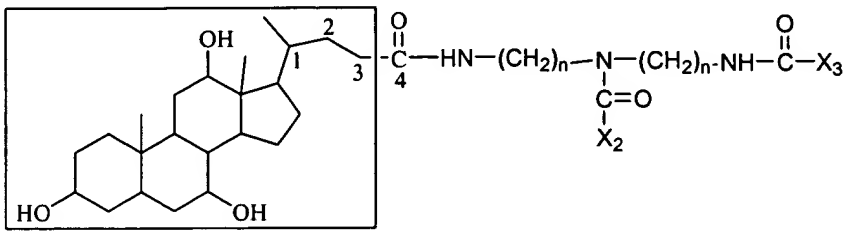
Cholic acid



Cholic acid group

Further, the Examiner alleges that cholic acid (with 4 carbons) attaches to the core of Formula I through a carbonyl group (1 carbon), for a total of 5 carbons. However, Applicants point out that the carbonyl group in the core of Formula I originates with the cholic acid starting material. As such, ***only 4 carbons*** are found between the pentose ring of the cholic acid group and the nitrogen adjacent to the carbonyl group. The attachment of one cholic acid group at X_1

to the core of Formula I, with the 4 carbons originating from the cholic acid starting material highlighted, is illustrated below.



Cholic acid group X_1 Core of Formula I

Referring to Example 12 of the instant application, Applicants assert that one skilled in the art would immediately recognize that during the synthesis of a compound of Formula I, when the cholic acid starting material is first reacted with isobutylchloroformate and subsequently reacted with 3-aminopropyl-3'-N-glucoamidopropyl-amine, the carbonyl group in the core of Formula I (carbon number 4 above) originates from the cholic acid starting material. As a result, one skilled in the art would have concluded that only 4 carbons separate the pentose ring of the cholic acid group and the nitrogen adjacent to the carbonyl group, contrary to the Examiner's allegation. Therefore, Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 112, first paragraph rejection.

In addition, the Examiner alleges that the structure of Impurity II alone is not adequate for claiming compounds having a core of Formula I with numerous combinations of X_1, X_2, and X_3. As previously explained, in order to expedite prosecution, Applicants have amended claim 41 to specify that X_1 and X_2 are both cholic acid groups, X_3 is a pentose monosaccharide group, and three carbons link the nitrogen atoms in the core of Formula I (n is 3). Applicants assert that a compound having the structure of Formula I as amended is clearly and adequately described in the specification. For instance, Example 12 specifically discloses the compound of Formula I (page 31, lines 15-19), and the specification teaches that a preferred compound of the present invention contains cholic acid groups at both X_1 and X_2, a saccharide group at X_3, and three carbons linking the nitrogen atoms in the core of Formula I (page 5, lines 2-10). A pentose monosaccharide group is clearly defined as a saccharide group found at X_3

(page 4, lines 31-32). Further, the structure of Formula I is supported by the presentation of mass spectral data that unambiguously identifies its structure (page 31, lines 25-27). Further, claim 54 uses IUPAC nomenclature to name and claim the compound. In view of the amendment to claim 41 and support thereof in the specification, Applicants submit that the compound corresponding to Formula I is clearly and sufficiently disclosed and claimed. Therefore, Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 112, first paragraph rejection.

B. Enablement Rejection

Claims 41-53 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

The Examiner alleges that the teachings in the specification are "generic to Formula I and do not specifically lead one of skill to the structure of Impurity II." Again, as previously explained, Applicants have amended claim 41 to specify that X_1 and X_2 are both cholic acid groups, X_3 is a pentose monosaccharide group, and three carbons link the nitrogen atoms in the core of Formula I (n is 3). Applicants assert that a compound having the structure of Formula I as amended is clearly and adequately described in the specification (page 4, lines 31-32; page 5, lines 2-10; page 31, lines 15-19 and 25-27). In view of the amendment to claim 41 and support thereof in the specification, Applicants submit that the specific compound corresponding to Formula I is clearly and sufficiently disclosed and claimed. Further, claim 54 uses IUPAC nomenclature to name and claim the compound. Therefore, Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 112, first paragraph rejection.

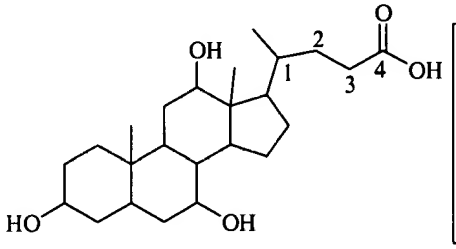
The Examiner also alleges that "the specification does not teach one of skill that Impurity II has two cholic acid groups" or that the cholic acids have a substitution resulting in an amide bond. In response, Applicants point out that page 5, lines 2-10 of the specification discloses a preferred embodiment of the present invention wherein X_1 and X_2 are both cholic

acid groups; and page 31, lines 15-19 discloses the compound 3'-N-gluconamidopropyl-3"-N-cholamidopropyl-N-cholamide, a compound that one skilled in the art would immediately appreciate as having **two** cholic acid groups. Further, one skilled in the art would also immediately recognize that during the synthesis of Formula I, the C-O single bond in the carboxylic group of cholic acid is substituted by a C-N amide bond upon attachment of cholic acid to the core of Formula I.

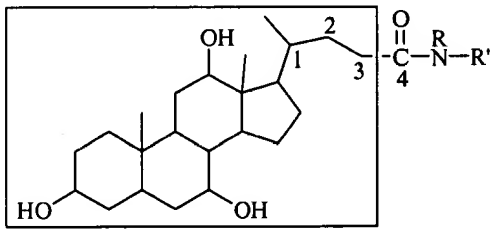
Further, claim 54 uses IUPAC nomenclature to name and claim the compound. As such, Applicants assert that the specification clearly and adequately discloses the structure of Formula I. Therefore, Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 112, first paragraph rejection.

Further, the Examiner alleges that the specification does not define a "cholic acid group." Applicants respectfully traverse this rejection.

Applicants assert that, to one skilled in the art, it is abundantly clear that the phrase "cholic acid group" means that it is no longer cholic acid, but rather a derivative of cholic acid. By comparing the two structures below of "cholic acid" and "cholic acid group," the Examiner can clearly see that the only difference is the substitution of an amide bond in the core of Formula I for the carboxyl group in the cholic acid starting material. One skilled in the art would recognize that the structure adjacent to the amide bond is no longer cholic acid, but rather a derivative of cholic acid, *i.e.*, a cholic acid group.



Cholic acid



Cholic acid group

The Examiner also alleges that cholic acid (with 4 carbons) attaches to the core of Formula I through a carbonyl group (1 carbon), for a total of 5 carbons. However, as previously discussed, Applicants point out that the carbonyl group in the core of Formula I originates with the cholic

acid starting material. As such, ***only 4 carbons*** are found between the pentose ring of the cholic acid group and the nitrogen adjacent to the carbonyl group.

Therefore, Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 112, first paragraph rejection.

In addition, the Examiner alleges that the structure of Impurity II alone is not adequate for claiming compounds having a core of Formula I with numerous combinations of X_1, X_2, and X_3. As previously explained, in order to expedite prosecution, Applicants have amended claim 41 to specify that X_1 and X_2 are both cholic acid groups, X_3 is a pentose monosaccharide group, and three carbons link the nitrogen atoms in the core of Formula I (n is 3). Applicants assert that a compound having the structure of Formula I as amended is clearly and adequately described in the specification (page 4, lines 31-32; page 5, lines 2-10; page 31, lines 15-19 and 25-27). Further, claim 54 uses IUPAC nomenclature to name and claim the compound. In view of the amendment to claim 41 and support thereof in the specification, Applicants submit that the compound corresponding to Formula I is clearly and sufficiently disclosed and claimed. Therefore, Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 112, first paragraph rejection.

III. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 41-53 were rejected as allegedly being indefinite because the structures encompassed by the claims are unclear. To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

As discussed above, Applicants respectfully suggest that the Examiner may have confused the source of the carbonyl carbon in the core of Formula I, thus leading to confusion about the number of carbons linking the pentose ring to the carbonyl carbon in the claimed compound. As Applicants understand it, the Examiner believes that the carbonyl carbon linking the cholic acid group to the rest of the structure does not originate with the starting cholic acid. And thus, when Applicants attach cholic acid to the remainder of the structure, *i.e.*, to the carbonyl group in the core of Formula I, the result is the addition of 4 carbons between the pentose ring of the cholic acid group and the carbonyl carbon (or, put another way, the addition

of 5 carbons total between the pentose ring and the nitrogen adjacent to the carbonyl group). Applicants respectfully disagree with this interpretation.

To the contrary, Applicants point out that the carbonyl group in the core of Formula I originates with the cholic acid starting material. As such, ***only 4 carbons*** are found between the pentose ring of the cholic acid group and the nitrogen adjacent to the carbonyl group. Referring to Example 12 of the instant application, Applicants assert that one skilled in the art would immediately recognize that during the synthesis of Formula I, the carbonyl group in the core of Formula I originates from the cholic acid starting material. As a result, one skilled in the art would have concluded that only 4 carbons separate the pentose ring of the cholic acid group and the nitrogen adjacent to the carbonyl group. Further, claim 54 uses IUPAC nomenclature to name and claim the compound. As such, Applicants believe that the specification clearly and adequately discloses the number of carbon atoms between the pentose ring of the cholic acid group and the carbonyl group in the core of Formula I. Therefore, Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 112, second paragraph rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

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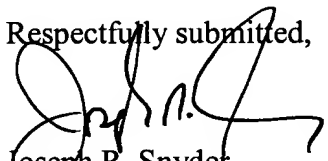
This IDS is being filed before the mailing date of the final Office Action or Notice of Allowance.

Please charge the IDS fee of $180 to Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



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